

REMARKS

The Advisory Action of August 17, 2010, and the Office Action of June 1, 2010 have been received and reviewed.

Claims 1-16 and 18-23 were previously pending and under consideration in the above-reference application. Each of claims 1-16 and 18-22 has been rejected.

Claims 3-6 have been canceled without prejudice or disclaimer.

Claim 23 is apparently drawn to allowable subject matter.

Reconsideration of the above-referenced application is respectfully solicited.

Rejections under 35 U.S.C. § 102(e)

Claims 1-16 and 18-22 have been rejected under 35 U.S.C. § 102(e) for reciting subject matter that is purportedly anticipated by the subject matter described in U.S. Patent Application Publication 2002/0044942A1 of Dopson (hereinafter "Dopson").

The Office's indication that the 35 U.S.C. § 102(e) rejection based on Dopson may be overcome by filing an affidavit in accordance with the requirements 37 C.F.R. § 1.131 is gratefully acknowledged. Such an affidavit will be prepared and executed when all further issues in the above-referenced application have been resolved.

Rejections under 35 U.S.C. § 103(a)

Claims 1-16 and 18-22 have been rejected under 35 U.S.C. § 103(a) for being directed to subject matter that is purportedly unpatentable over the subject matter taught by U.S. Patent 5,080,895 to Tokoro (hereinafter "Tokoro"), in view of teachings from U.S. Patent 5,840,700 to Kirkpatrick (hereinafter "Kirkpatrick").

There are several requirements in establishing a *prima facie* case of obviousness against the claims of a patent application. All of the limitations of the claim must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Even then, a claim "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396

(2007). The Office must also establish that one of ordinary skill in the art would have had a reasonable expectation of success that the purported modification or combination of reference teachings would have been successful and, thus, some reason to predict that the combination of reference teachings would work. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Accordingly, there must also “be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.*, quoting *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006). That reason must be found in the prior art, common knowledge, or derived from the nature of the problem itself, and not based on the Applicant’s disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006). A mere conclusory statement that one of ordinary skill in the art would have been motivated to combine or modify reference teachings will not suffice. *KSR* at 1396.

Independent claims 1 and 20, as amended, are both directed to methods for causing treated animals to elicit T cell mediated immune responses. These methods include administering an extract of an egg to a treated animal. The extract, which consists of egg yolk, includes transfer factor.

It has been asserted that Tokoro teaches a “transfer factor-like component” that is not an antibody, that has a lower molecular weight than antibodies, and that is specific to a particular antigen. Final Office Action of June 1, 2010, page 5. By admitting that “the immunological functions of the transfer factor-like component... are not known” (col. 7, lines 44-47), Tokoro created uncertainty as to whether or not the transfer factor-like component (that was purportedly in the egg, but couldn’t have been transfer factor against any of the bacterial antigens specified by Tokoro) could cause a treated animal to elicit a T cell mediated immune response. Thus, as of the earliest date to which a claim for priority has been made in the above-referenced application, one of ordinary skill in the art would have had no reason to predict that a composition of the type recited by independent claim 1 or independent claim 20 could be used to effect the treatment methods recited by these claims.

Further, it should be recognized that many uncertainties remain in the field of immunology and, therefore, that the art is largely unpredictable. For example, as is already

evident from the inability of certain antigens (*i.e.*, all of the specific bacterial antigens identified by Tokoro) to cause a host to elicit a T cell immune response, there is a particularly low level of predictability as to whether or not any particular antigen will cause a non-mammalian source animal, such as a chicken, to elicit a T-cell immune response, to produce transfer factor, or to produce eggs that include that transfer factor.

Kirkpatrick does not provide the missing predictability. Kirkpatrick provides no teaching or suggestion that a chicken could produce transfer factor; that, even if a chicken could produce transfer factor (or a transfer factor-like component), the transfer factor would be present in eggs; or that, even if transfer factor (or the transfer factor-like component) were present in eggs, it could cause a treated animal to elicit a T cell mediated immune response. The teachings of Kirkpatrick are limited to transfer factor obtained from the blood (*e.g.*, by way of blood-carrying organs) of mammalian sources.

Without the requisite predictability, the teachings of Tokoro and Kirkpatrick do not support a *prima facie* case of obviousness under any of the rationales presented in M.P.E.P. § 2143.

Moreover, it is respectfully noted that Kirkpatrick teaches away from the use of compositions that include anything other than transfer factor, such as the compositions of independent claims 1 and 20 that include "other egg yolk proteins." For example, at col. 4, lines 49-56, Kirkpatrick suggests that transfer factor obtained from natural sources does not provide a desired immune response in a treated animal. At col. 4, lines 57-62, Kirkpatrick suggests that molecules other than transfer factor (*e.g.*, other egg yolk proteins, etc.) require "extraordinary precaution to maintain ... the material." Since Kirkpatrick teaches away from the subject matter recited by amended independent claims 1 and 20, Kirkpatrick cannot be relied upon to establish a *prima facie* case of obviousness against either of these claims, or against any of their dependent claims.

In view of the foregoing, it is respectfully submitted that, under 35 U.S.C. § 103(a), each of claims 1-4, 7-18, and 20-24 is allowable over the subject matter taught and suggested by

Tokoro and Moss. Withdrawal of the 35 U.S.C. § 103(a) rejections of these claims is, therefore, respectfully solicited.

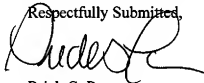
Allowable Subject Matter

The indication that claim 23 is drawn to allowable subject matter is noted with appreciation. Claim 23 has not yet been amended to independent form, as independent claim 1, from which claim 23 depends, is believed to be allowable.

CONCLUSION

It is respectfully submitted that each of claims 1-16 and 18-23 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully Submitted,



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